K090216

SEP 18 2009

510(k) Summary of Safety and Effectiveness

Applicant Name and Address: Collagen Matrix, Inc.
509 Commerce Street
Franklin Lakes, New Jersey 07417

Contact Person: Peggy Hansen, RAC
Vice President, Clinical, Regulatory, QA, and Marketing
Tel: (201) 405-1477
Fax: (201) 405-1355

Date of Summary: May 1, 2009

Device Common Name: Resorbable Collagen Membrane

Device Trade Name: Collagen Dental Membrane IV

Device Classification Name: Barrier, animal source, intraoral
872.3930
NPL
Class II

Predicate Device(s): Collagen Dental Membrane – Conformable II
K062881

Bio-Gide™ Resorbable Bilayer Membrane for Guided Tissue and Bone Regeneration
K050446

Tutodent® Dental Membrane
CopiOs™ Pericardium Membrane
K073097

Description of the Device

Collagen Dental Membrane IV is a white, nonfriable, conformable, resorbable, membrane matrix consisting of highly purified type I and III collagen derived from bovine dermis. It is flexible and conforms to the contours of the defect site. Collagen Dental Membrane IV is supplied sterile, non-pyrogenic, in various sizes, and for single use only.

Intended Use

Collagen Dental Membrane IV is intended for use in oral surgical procedures as a resorbable membrane material for use in augmentation around implants placed in immediate extraction sockets, delayed extraction sockets; localized ridge augmentation for later
implantation; alveolar ridge reconstruction for prosthetic treatment; filling of bone defects; guided bone regeneration in dehiscence defects and guided tissue regeneration procedures in periodontal defects.

Summary/Comparison of Technical Characteristics

Collagen Dental Membrane IV and its predicates have similar technological characteristics. In particular, the Collagen Dental Membrane IV and its predicate are similar with respect to intended use, form, animal source, sizes, thickness, physical integrity, permeability and conformability.

Safety

Collagen Dental Membrane IV has been evaluated in a number of in vitro and in vivo tests to assess its safety/biocompatibility. The device passed all applicable FDA Blue Book Memorandum G95-1and ISO 10993-1 testing for the biological evaluation of medical devices.

Conclusion

The results of the *in vitro* product characterization studies and *in vivo* animal studies show that Collagen Dental Membrane IV is safe and substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

SEP 18 2009

Ms. Peggy Hansen
Vice President, Clinical, Regulatory Quality Assurance
Collagen Matrix, Incorporated
509 Commerce Street
Franklin Lakes, New Jersey 07417

Re: K090216
Trade/Device Name: Collagen Dental Membrane IV
Regulation Number: 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: II
Product Code: NPL
Dated: September 4, 2009
Received: September 9, 2009

Dear Ms. Hansen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

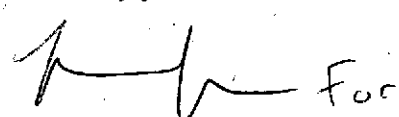
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Susan Runner, D.D.S., M.A.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K090216

Indications for Use

510(k) Number (if known): K090216

Device Name: Collagen Dental Membrane IV

Indications for Use:

Collagen Dental Membrane IV is intended for use in oral surgical procedures as a resorbable membrane material for use in augmentation around implants placed in immediate extraction sockets, delayed extraction sockets; localized ridge augmentation for later implantation; alveolar ridge reconstruction for prosthetic treatment; filling of bone defects; guided bone regeneration in dehiscence defects and guided tissue regeneration procedures in periodontal defects.

Prescription Use X AND/OR Over-The-Counter Use ____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Kevin Mulley for MSP

Division Sign-Off)
ivision of Anesthesiology, General Hospital
nfection Control, Dental Devices

10(k) Number: K090216